

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Sharif et al.

U.S. Serial No. NYA

Filed: April 14, 2004

Examiner: NYA

Group Art Unit: NYA

For: Methods of Treating Dry Eye  
Disorders

**CERTIFICATE OF MAILING**  
**BY EXPRESS MAIL**

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April 14, 2004  
Date  
Jeanne Burke  
Jeanne Burke

**INFORMATION DISCLOSURE STATEMENT**  
**PURSUANT TO 37 C.F.R. 1.56**

MS Patent Application  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. 1.56. Applicants submit the following patents, articles and other information listed on the attached PTO Form 1449.

Because the PTO has waived the requirement under 37 CFR 1.98(a)(2) to submit copies of each cited U.S. patent and patent application publication in all U.S. national patent applications filed after June 30, 2003, none are enclosed. Only copies of cited foreign patent documents and non-patent literature are enclosed.

Applicants request that the listed references be considered during prosecution of this application, and that the references appear among the "References Cited" on any patent issuing herefrom.

Respectfully submitted,

ALCON

4/14/04  
Date

Patrick M. Ryan  
Patrick M. Ryan  
Registration No. 36,263

Alcon Research, Ltd.  
R&D Counsel Q-148  
6201 South Freeway  
Fort Worth, Texas 76134-2099  
(817) 551-3066

Attorney Docket No.: 2489

| Form PTO-1449 U.S. Dept. of Commerce<br><br>Patent & Trademark Office<br><br><b>LIST OF DOCUMENTS CITED BY APPLICANT</b><br><br>(Use several sheets if necessary) |    | ATTY. DOCKET NO.<br><br>2489  |          | SERIAL NO.<br><br>NYA |       |          |                            |
|---|----|---|----------|-----------------------|-------|----------|----------------------------|
|   |    | APPLICANT<br><br>Sharif et al.  |          |                       |       |          |                            |
|   |    | FILING DATE<br><br>April 14, 2004   |          | GROUP<br><br>NYA      |       |          |                            |
| U.S. PATENT DOCUMENTS   |    |   |          |                       |       |          |                            |
| EXAMINER INITIAL  |    | DOCUMENT NUMBER   | DATE     | NAME                  | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|   | AA | 4,131,651   | 12/26/78 | Shah et al.           | 424   | 78       |                            |
|   | AB | 4,370,325   | 01/25/83 | Packman               | 424   | 245      |                            |
|   | AC | 4,409,205   | 10/11/83 | Shively               | 424   | 78       |                            |
|   | AD | 4,744,980   | 05/17/88 | Holly                 | 424   | 78       |                            |
|   | AE | 4,818,537   | 04/04/89 | Guo                   | 424   | 427      |                            |
|   | AF | 4,883,658   | 11/28/89 | Holly                 | 424   | 80       |                            |
|   | AG | 4,914,088   | 04/03/90 | Glonek et al.         | 514   | 76       |                            |
|   | AH | 4,966,773   | 10/30/90 | Gressel et al.        | 424   | 489      |                            |
|   | AI | 5,041,434   | 08/20/91 | Lubkin                | 514   | 182      |                            |
|   | AJ | 5,075,104   | 12/24/91 | Gressel et al.        | 424   | 78.04    |                            |
|   | AK | 5,174,988   | 12/29/92 | Mautone et al.        | 424   | 45       |                            |
| FOREIGN PATENT DOCUMENTS  |    |   |          |                       |       |          |                            |
|   |    | DOCUMENT NUMBER   | DATE     | COUNTRY               | CLASS | SUBCLASS | TRANSLATION                |
|   |    |   |          |                       |       |          | YES      NO                |
|   | AL | EP 1 123 936 A1   | 08/16/01 | EPO                   |       |          |                            |
|   | AM | EP 1 243 271 A1   | 09/25/02 | EPO                   |       |          |                            |
|   | AN | WO 00/03705   | 01/27/00 | PCT                   |       |          |                            |
|   | AO | WO 02/48135 A1  | 06/20/02 | PCT                   |       |          | X<br>(abstract only)       |
|   | AP |   |          |                       |       |          |                            |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |   |          |                       |       |          |                            |
|   | AR | Fukuda et al., "Inhibition of Allergic Dermal Inflammation by the Novel Imidazopyridazine Derivative TAK-427 in a Guinea Pig Experimental Model of Eczema," <i>J. of Pharmacology and Experimental Therapeutics</i> , Vol. 303(3); pp. 1283-1290 (2002) |          |                       |       |          |                            |
|   | AS | Lemp et al., "Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes," <i>CLAO Journal</i> , Vol. 21(4), pp. 221-231 (1995)  |          |                       |       |          |                            |
|   | AT | McCulley et al., "Tear Film Structure and Dry Eye," <i>Contactologia</i> , Vol. 20, pp. 145-149 (1998)  |          |                       |       |          |                            |

EXAMINER

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

| Form PTO-1449 U.S. Dept. of Commerce<br><br>Patent & Trademark Office<br><br><b>LIST OF DOCUMENTS CITED BY APPLICANT</b><br><br>(Use several sheets if necessary) |    | <b>ATTY. DOCKET NO.</b><br><br>2489  |          | <b>SERIAL NO.</b><br><br>NYA |       |          |                            |
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| EXAMINER INITIAL  |    | DOCUMENT NUMBER  | DATE     | NAME                         | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|   | BA | 5,278,151  | 01/11/94 | Korb et al.                  | 514   | 76       |                            |
|   | BB | 5,290,572  | 03/01/94 | MacKeen                      | 424   | 602      |                            |
|   | BC | 5,294,607  | 03/15/94 | Glonek et al.                | 514   | 76       |                            |
|   | BD | 5,371,108  | 12/06/94 | Korb et al.                  | 514   | 762      |                            |
|   | BE | 5,578,586  | 11/26/96 | Glonek et al.                | 514   | 76       |                            |
|   | BF | 5,696,166  | 12/09/97 | Yanni et al.                 | 514   | 573      |                            |
|   | BG | 5,800,807  | 09/01/98 | Hu et al.                    | 424   | 78.04    |                            |
|   | BH | 5,958,912  | 09/28/99 | Sullivan                     | 514   | 177      |                            |
|   | BI | 6,153,607  | 11/28/00 | Pflugfelder et al.           | 514   | 178      |                            |
|   | BJ | 6,248,740  | 06/19/01 | Kawano et al.                | 514   | 248      |                            |
|   | BK | 2004/0058875 A1  | 03/25/04 | Gamache                      | 514   | 15       |                            |
| <b>FOREIGN PATENT DOCUMENTS</b>   |    |  |          |                              |       |          |                            |
|   |    | DOCUMENT NUMBER  | DATE     | COUNTRY                      | CLASS | SUBCLASS | TRANSLATION                |
|   |    |  |          |                              |       |          | YES    NO                  |
|   | BL |  |          |                              |       |          |                            |
|   | BM |  |          |                              |       |          |                            |
|   | BN |  |          |                              |       |          |                            |
|   | BO |  |          |                              |       |          |                            |
|   | BP |  |          |                              |       |          |                            |
| <b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>   |    |  |          |                              |       |          |                            |
|   | BR | Marsh et al., "Topical Nonpreserved Methylprednisolone Therapy for Keratoconjunctivitis Sicca in Sjogren Syndrome," <i>Ophthalmology</i> , Vol. 106(4), pp. 811-816 (1999)   |          |                              |       |          |                            |
|   | BS | Shine et al., "Keratoconjunctivitis Sicca Associated with Meibomian Secretion Polar Lipid Abnormality," <i>Arch. Ophthalmol.</i> , Vol. 116, pp. 849-852 (1998)  |          |                              |       |          |                            |
|   | BT | Tauber et al., "A Dose-Ranging Clinical Trial to Assess the Safety and Efficacy of Cyclosporine Ophthalmic Emulsion in Patients with Keratoconjunctivitis Sicca," <i>Lacrimal Gland, Tear Film and Dry Eye Syndromes 2</i> , edited by Sullivan et al., Plenum Press, New York, pp. 969-972 (1998) |          |                              |       |          |                            |

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